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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,376	09/10/2003	Dan Nilsson	NILSSON=6B	5425

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EXAMINER

AFREMOVA, VERA

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 01/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/658,376	Applicant(s) NILSSON, DAN	
	Examiner Vera Afremova	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6,7,9-11,27 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6, 7, 9-11, 27 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 6, 7, 9-11, 27 and 30 as amended and new (11/01/2005) are pending and under examination.

Deposit

The deposit requirement for strains *Lactococcus lactis subsp. lactis* DN221 (DSM 11034) and *Lactococcus lactis subsp. lactis* DN227 (DSM 11040) have been met in the response papers filed 11/01/2005.

Claim Objections

Claims 9-11 are objected to because of the following informalities:

Claims 9 depended on canceled claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Indefinite

Claim 11 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claimed term “essentially” remains indefinite with respect to the non-essential differences between strains as claimed. It is suggested to write, for example: “...strain having all of the identifying characteristics...”

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 6, 7, 9, 10, 27 and 30 as amended remain/are rejected under 35 U.S.C. 102(b) as being anticipated by Hugenholtz (IDS reference; "Citrate metabolism in lactic bacteria". FEMS Microbiology Reviews 1993, 12, 165-178) or by Starrenburg et al. ("Citrate fermentation by *Lactococcus* and *Leuconostoc spp.*" Applied and Environmental Microbiology. December, 1991. Vol. 57, No. 12, pages 3535-3540) in the light of evidence by ATCC Catalogue.

Claims are directed to a Pfl-defective mutant (lacking enzyme pyruvate formate lyase) of lactic acid bacterium selected from the group of species belonging to *Lactobacillus*, *Streptococcus*, *Bifidobacterium*, *Pediococcus* and *Lactococcus* including *Lactococcus lactis subsp. lactis/diacetalicus*. The claimed bacterium is characterized relatively to the parent or wild-type strain by at least one characteristics such as that it does not produce formate under anaerobic conditions, does not produce ethanol under anaerobic conditions, is characterized by production of acetolactate-derived metabolite(s), is characterized by capability to grow on M17 medium under aerobic conditions and has reduced growth on M17 medium under anaerobic conditions. The claimed bacterium is made by selection of mutants that does not growth on acetate-containing medium under anaerobic conditions. Some claims are further drawn to the strain capable of producing acetoin. Some claims are further drawn to a starter composition comprising the PFL defective lactic acid bacterium.

The reference by Hugenholtz discloses a PFL defective lactic acid bacterium belonging to *Leuconostoc* species that are lacking enzyme PFL (page 171, col.2, par. 3, lines 5-8). In view of

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the Fig. 1 teaching, the PFL lacking mutant does not produce formate, acetate and ethanol and it is characterized by production of acetolactate-derived metabolite(s) including acetoin as required for the claimed bacterium. The PFL defective mutant in a culture medium is a starter composition within the meaning of the claims.

The reference by Hugenholtz indicates the teaching by Starrenburg et al. for additional disclosure about the PFL defective lactic acid bacterium belonging to *Leuconostoc* species such as “*Leuconostoc* 60” that does not produce formate under anaerobic conditions (see the reference by Starrenburg et al. at table 1, page 3537), does not produce ethanol but produces acetolactate-derived metabolite(s) including acetoin and butanediol. The PFL defective mutant in a culture medium is a starter composition within the meaning of the claims

Although characteristics of the parent or wild type strains of the referenced PFL mutants are not indicated or disclosed, the relative enhancement and/or relative differences of claimed features cannot be determined and they would not be meaningful unless some specific and particular strains are claimed.

Although it is uncertain how the referenced bacteria have not been made or selected, they are the PFL-defective mutants and, thus, they are characterized by the same features that are required during selection method as encompassed by the claims.

Although the referenced bacteria are characterized as belonging to *Leuconostoc*, the lactic bacteria belonging to *Leuconostoc*, *Lactobacillus*, *Streptococcus*, *Bifidobacterium*, *Pediococcus*, *Lactococcus* including *Lactococcus lactis* subsp. *lactis/diacetalicus* have been frequently cross-identified and reclassified between these genera and species (as demonstrated by ATCC catalogue, see pages 68, 199, 205, 264 and 346) and, thus, there is a reasonable believe that the

pfl defective lactic bacteria of the cited references might be assigned to any and all of the presently claimed genera and/or species.

Response to Arguments

Applicant's arguments filed 11/01/2005 have been fully considered but they are not all found persuasive.

The deposit requirement for strains *Lactococcus lactis subsp. lactis* DN221 (DSM 11034) and *Lactococcus lactis subsp. lactis* DN227 (DSM 11040) have been met in the response papers filed 11/01/2005.

Claim rejection under 35 U.S.C. 102(b) as being anticipated by Mat-Jan et al. has been withdrawn because the cited reference teaches *E.coli* strain as a PFI-defective bacterium that does not belong to the group of lactic bacteria.

With regard to the claim under 35 U.S.C. 102(b) as being anticipated by Hugenholtz or by Starrenburg et al in the light of evidence by ATCC Catalogue Applicants argue that the claimed group of pfl-defective bacteria can not be anticipated by the pfl-defective mutants assigned to the genus of *Leuconostoc* sp. taught by Hugenholtz or by Starrenburg et al. because the claimed bacteria belong to the group(s) taxonomically distinct from *Leuconostoc*. Yet, the cited ATCC Catalogue (as explained above) and the cited reference by Hugenholtz (page 166, col. 1 at section "Metabolic pathways") demonstrate that the taxonomic re-assignment within the group of lactic bacteria can be changed but the metabolic pathways of lactic bacteria are the same. The main functional characteristic and the main metabolic activity of lactic bacteria is fermentation of carbohydrates and non-carbohydrate substrates with lactic acid as a major end

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product and additional minor fermentation products including formate, acetate and ethanol that are produced via pyruvate formate lyase (Hugenholtz' reference, Fig. 1). Thus, the lactic bacteria would remain and/or be reclassified within the same group of lactic bacteria in the presence and in the absence of PFL enzyme. Applicants appear to argue that the claimed bacterial is required to satisfy the claimed clauses (i)-(v). However, all claimed clauses are result of PFL deficiency in all lactic bacteria including claimed genera and genus of *Leuconostoc*. The pfl-deficient mutant of lactic bacteria is known in the prior art regardless its current "taxonomic" name. Applicants appear to argue that *Leuconostoc* species have been finally classified as distinct from other group of lactic bacteria on a basis of 16sRNA sequence in 2005. Yet, within the timing of the cited reference and the moment of filing of the instant application the fact of re-classification within the whole group of lactic bacteria including claimed bacteria and *Leuconostoc* remains valid. Moreover, 16sRNA sequence has no functional value for fermentative properties of lactic bacteria. One of skill in the art would not look into 16sRNA sequence for selection of PFL-deficient mutant of lactic bacteria. The lactic bacteria belonging to *Leuconostoc*, *Lactobacillus*, *Streptococcus*, *Bifidobacterium*, *Pediococcus*, *Lactococcus* including *Lactococcus lactis subsp. lactis/diacetalicus* have been frequently cross-identified and reclassified between these genera and species (as demonstrated by ATCC catalogue, see pages 68, 199, 205, 264 and 346) and, thus, there is a reasonable believe that the pfl defective lactic bacteria of the cited references might be assigned to any and all of the presently claimed genera and/or species. Thus, the claims 6, 7, 9, 10, 27 and 30 are properly rejected.

Claim 11, drawn to the specific applicants' isolates deposited in DSM, is free from prior art and might be allowable after resolution of 112-2 issue(s).

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.


The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

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January 3, 2006



VERA AFREMOVA
PRIMARY EXAMINER